Vitalograph® K073155

VITALOGRAPH (IRELAND) LIMITED, ENNIS INDUSTRIAL ESTATE, GORT ROAD, ENNIS, CO. CLARE.
TELEPHONE: (065) 6864100. FAX: (065) 6829289.

510K Summary

as required by 21 CFR 807.92

JUN - 4 2008

1. Company Information:
   Name: Vitalograph (Ireland) Ltd
   Address: Gort Road Business Park, Ennis, Co Clare, Ireland.

   Tel: +353656864100
   Fax: +353656829289.

2. Contact Person / Official Correspondent:
   Mr. Tom J Healy
   Regulatory Affairs / Quality Assurance Manager

3. Date of Submission:
   October 04, 2007.

4. Device Trade Name:
   Vitalograph Model 4000. {asma-1 and copd-6}

5. Common / Usual name:
   Electronic Peak Flow Meter, handheld spirometer,

6. Classification number:
   Spirometer as classified in Class II per 21 CFR 868.1840

   Extracted from 21 CFR 868 on September 28, 2007:

Subpart B--Diagnostic Devices

Sec. 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs.

(b) *Classification.* Class II (performance standards).

7. Predicate Device:

Manufacturer	: Micro Medical
Device Name	: PulmoLife
510(k) No	: K061283

8. Description of Device:
   The Vitalograph Model 4000 series {asma-1 and copd-6} are battery powered handheld electronic spirometers used to measure expired Peak Flow and forced expired volume after one second {FEV1}.. The results can aid in the diagnosis of Asthma and COPD in patients.

   All variants {asma-1 and copd-6} within the range use the very same operating

principle, LCD, Buttons, and Mouldings. Items that may vary within the range are the list of parameters that the different variants display. I.e. Asma-1 displays FEV1 and PEF, whilst the copd-6 displays FEV1 and FEV6 only.

A uni-directional rotating vane with flow sensor to measure lung function is used. The measurements are taken via expiration into the unit flowhead, which is In-turn displayed onto an LCD.

Navigation is allowed via the use of four buttons {Up, Down, Enter/Select and power On/Off}

9. Intended use:

To be used by the asthma / copd patient at home to monitor the condition.
To be used in General Practitioner's clinic with disposable mouthpieces.
The Model 4000 range is intended as to compete directly with competitor's electronic peak flow meters and COPD screening devices.

10. Technological Characteristics

The Vitalograph Model 4000, as with the Pulmo life uses a rotating vane to measure lung function. All are intended to be handheld, portable devices. All are battery powered and operated via four buttons {On / Off, Up, Down, Enter / Select}.

The primary difference between the Model 4000 and the predicate device is the inclusion of Bluetooth and/or USB in the Model 4000 for data export / printing where the predicate uses bi- directional IR as a means of communication.

Also, the Model 4000 range allows the General Practitioner to set expected predicted values. These entries are not adjustable by the end user.

	Vitalograph Model 4000 [asma-1 /copd-6) Specifications	PulmoLife Specifications
Volume Range:	0-9.99 Litres	0-8Litres
Flow Range	0-840 L/minute	0-14 Litres / second {0-840 L/minute}
Accuracy FEV1:	+/- 3%	+/- 3%
Accuracy FEV6	+/- 3%	+/- 3%
Accuracy PEF	+/-5%	N/A
Technology:	Rotor stator design	Rotor stator design
Lung age	Asma-1 :NO Copd-6: Yes	Yes
Set Predicted / reference values	Yes {by qualified person, not user}	No
Memory Type:	Non-volatile Colour zones: 3 or 4 Zone {Green, Yellow, Red}. + Orange in 4 zone plan Quality Factor: Warning & indicator for cough or poor blow	Non-volatile Color Zone: 3 Color Zones (Green, Yellow, Red) Quality Factor: Warning & indicator for cough or abnormal blow
Sounds:	Audible beeps emitted during power on, whilst performing a test, at end of test and for each key press.	Audible beeps emitted during power on, at end of test and for each key press.

Communication:	Bluetooth and/or USB to be incorporated.	Bi-directional Infra Red port (RS232 format)
Battery Warnings:	On-screen Battery Full, Half Full and Battery Empty (Flashing icon)	Low Battery warning and audible beep.
Battery Type:	2 x 1.5v AAA	3v Li coin cell (CR2450)
Autopowerdown	2 minutes	4 minutes
Dimensions:	113 x 63 x 48 mm	131 x 59 x 38 mm
Weight:	Incl batteries 83g net, packaged 125g	Incl batteries 96 g, complete with accessories 260g
Material Type:	PC/ABS	
Back Pressure:	Better than 0.15kPa/L/s at 14L/s	
Operating Temp:	17-37°C per ATS 2005.	0 to 40°C
Storage Temp:	0 - 50 °C	(-20) to 70oC
Humidity:	10 - 95% relative humidity	30 - 90% relative humidity
Standard:	ATS 2005, ISO 23747:2007 for PEF (formerly EN13826:2003.	ATS 2005
Compliance:	EN 60601 (EN 60601-1-1 and EN 60601-1-2) IEC 61000-4-2, IEC61000-4-3 (battery operated)	EN 60601 (EN 60601-1-1 and EN 60601-1-2)
Regulatory:	FDA - 510(k) CE (0086) Class 2a	FDA - 510(k)
Warranty:	1 Year	7 months (batteries not included)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

Mr. Tom J. Healy
Regulatory Affairs & Quality Assurance Manager
Vitalograph (Ireland) Limited
Gort Road Business Park
Ennis, Co. Clare
IRELAND

Re: K073155
Trade/Device Name: Vitalograph Model 4000 (ASMA-1 and COPD-6)
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: May 22, 2008
Received: May 27, 2008

Dear Mr. Healy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073155

Device Name: VITALOGRAPH MODEL 4000.

Indications For Use:

The Vitalograph Model 4000 is a battery powered, handheld electronic spirometer used to measure Peak Flow [PEF] and Forced expired volume [FEV].

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073155